

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in May 2016.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-439

Trade Name: Inteprity™
Ingredients: Avilamycin
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: May 2, 2016
Status: VFD
Route: Oral, in feed
Species: Broiler chickens
Drug Form: Type A medicated article
Concentration: 45.4 g/lb (100 g/kg)
Indications: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.
Exclusivity: 3 years

NADA Number: 141-457

Trade Name: ENTYCE®
Ingredients: Capromorelin
Sponsor: Aratana Therapeutics, Inc.
Approval Date: May 16, 2016
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Oral solution
Concentration: Each milliliter of solution contains 30 milligrams (mg) capromorelin.
Indications: For appetite stimulation in dogs.
Exclusivity: 5 years
Patent: Patent Number 6,673,929 Expiration date: February 25, 2020

NADA Number: 141-463

Trade Name: onsior™
Ingredients: Robenacoxib
Sponsor: Elanco US, Inc.
Approval Date: May 17, 2016
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablets
Concentration: Tablets contain 10, 20, or 40 mg of robenacoxib.
Indications: For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs \geq 5.5 lbs (2.5 kg) and \geq 4 months of age; for up to a maximum of 3 days.
Exclusivity: 3 years
Patent: Patent Number 6,291,523 Expiration date: February 13, 2021
6,310,099 August 25, 2018

ANADA Number: 200-536

Trade Name: Mometavet®
Pioneer: Mometamax™
Ingredients: Gentamicin sulfate, USP; mometasone furoate anhydrous, USP; and clotrimazole, USP

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Sponsor: Med-Pharmex, Inc.
Approval Date: May 17, 2016
Status: Rx
Route: Topical (Otic)
Species: Dogs
Drug Form: Suspension
Concentration: Each gram contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate anhydrous, USP equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP.
Indications: For the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase- positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

ANADA Number: 200-596

Trade Name: Tilmovet® 90 and Rumensin® 90
Pioneer: Pulmotil® 90 and Rumensin® 90
Ingredients: Tilmicosin phosphate and monensin
Sponsor: Huvepharma EOOD
Approval Date: May 24, 2016
Status: VFD
Route: Oral, in feed
Species: Cattle fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Tilmicosin phosphate – 90.7 g/lb
Monensin – 90.7 g/lb
Indications: 1) For prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.
2) For improved feed efficiency and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.